Contains Nonbinding Recommendations

Draft Guidance on Phentermine Hydrochloride

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient: Phentermine Hydrochloride

Form/Route: Capsule/Oral

Recommended studies:

Phentermine Hydrochloride is a DESI[1] effective drug for which there are no known or suspected bioequivalence problems, and as such is rated "AA" in the FDA/CDER's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book").

Analytes to measure: Not Applicable

Bioequivalence based on (90% CI): Not Applicable

Waiver request of in-vivo testing: 15 mg, 30 mg and 37.5 mg strengths based on acceptable formulation data and in vitro dissolution testing under 21 CFR § 320.22(c).

NOTE: Please submit one ANDA for Phentermine Hydrochloride Capsule USP, 15 and 30 mg, and one for Phentermine Hydrochloride Capsules USP, 37.5 mg.

Dissolution test method and sampling times:

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at http://www.fda.gov/cder/ogd/index.htm. Please find the dissolution information for this product at this website. Please conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the application.

[1] Drug Efficacy Study Implementation